Use of Radiolabeled Platelets for Assessment of In Vivo Viability of Platelet Products

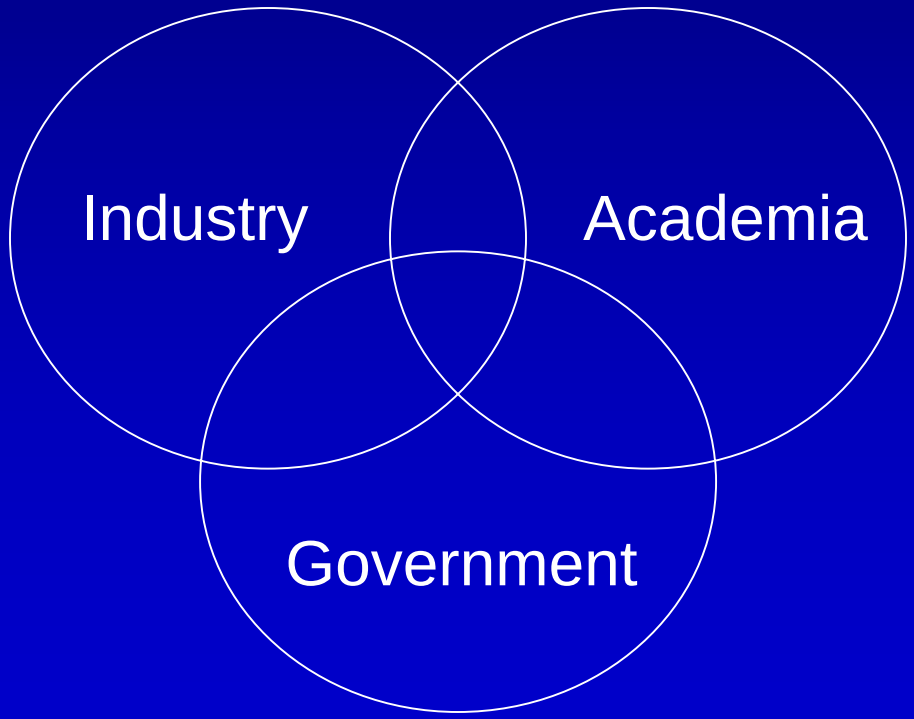
FDA perspective

Jaroslav G. Vostal, MD, PhD

Laboratory of Cellular Hematology

Division of Hematology, OBRR, CBER, FDA

2004 Workshop on Use of Radiolabeled Platelets for Assessment of In Vivo Viability of Platelet Products: A collaborative effort



Workshop sponsors

- Hitchcock Foundation, Dartmouth-Hitchcock Medical Center

- Baxter
- Cerus
- Gambro
- Pall/ Medsep
- Terumo

Steering committee

- Jim AuBuchon
- Scott Murphy
- Edward Snyder
- Salim Haddad
- Jaro Vostal

- BEST (Biomedical Excellence for Safer Transfusion Working Party of ISBT)

FDA is committed to a “gold standard” for platelet product performance

- The regulatory review process becomes uniform and less subjective
- Common research protocols will minimize differences in methodology and improve inter-laboratory compatibility
- Fixed standard can maintain the same level of platelet product quality over time
- Uniform protocols and accepted standards will facilitate product development in a competitive but fair environment

FDA plan for implementation of the new approach to radiolabeling studies

- FDA will recommend that future studies are performed using fresh platelets as the control
- The acceptance criteria (% recovery and survival) will be presented at July 2004 BPAC meeting to obtain concurrence of the committee
- Plan to incorporate the new approach to radiolabeling into a revision of the 1999 Draft Guidance on Platelet Testing

FDA current thinking on platelet radiolabeling studies

- Protocol design
  - Follow design agreed on in workshop discussion
- Study size
  - Based on statistics
  - Anticipate 20-40 volunteers
- The acceptance criteria, based on the discussion at this workshop, will be____% of fresh for recovery and ___% of fresh for survival.

Is Failure an Option?

What happens when a platelet product fails the criteria?

- May not be the “end of the road”
- Products with alternative merits (pathogen reduced or extended shelf life) could be licensed if their benefits outweigh their shortcomings
- Products that do not meet criteria can still be licensed but will need to have labeling that indicates how they differ from platelets
- May need to be called something other than “platelets, classic”
- Each alternative product will be considered on a case by case basis

Future prospects (wish list)

- Continue search for the “Holy Grail” (an in vitro or animal test that will replace human in vivo radiolabeling studies for platelets)
- Find alternative cell labeling methods that could replace radioactivity
- Find synthetic substitute to natural platelets that will have a long shelf life, be pathogen free and be non-alloimmunogenic